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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/601,856
Filing Date: June 23, 2003
Appellant(s) : ZHANG ET AL.

Milton Honig
Registration Number 28,617
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 25, 2006 appealing from the Office action mailed March 8, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The examiner notes that appellant has filed appeal briefs in US Patent Application 10/347982; 10374300; 10/601731, and 10/767679. Although these copending applications are not related to this application as continuations, the copending applications are directed to compositions comprising malonic acid salts present as half neutralized or fully neutralized acids in specific molar ratios.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,641,495	JOKURA et al	6-1997
JP 61215318	SADASHIGE et al	9-1986

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A) Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495).

Jokura teaches a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) a salt of a dicarboxylic acid. See abstract.

Jokura teaches examples of the dicarboxylic acid (B) include **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid . The dicarboxylic acid salt (C) include alkali metal (for example, sodium, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; alkanolamine (for example, **triethanolamine**) salts; basic amino acid (for example, lysine, arginine) salts and **ammonium** salts. These dicarboxylic acid salts may be added in the form of a salt at the step of the preparation of the skin cosmetic of the present invention. Alternatively, an acid may be added followed by the addition of an alkali (sodium hydroxide, etc.) to thereby form the aimed salt via *neutralization* in the system. To achieve a sufficient moisturizing effect while avoiding excessive irritation, it is preferable that the total content of these components (B) and (C), in terms of the acid, in the skin cosmetic of the present invention falls within a range of from 0.01 to 20% by

weight, still preferably from 0.05 to 15% by weight and still preferably 0.01 to 10% by weight. To achieve a sufficient moisturizing effect while avoiding irritation due to the acid, it is preferable that the molar ratio of the components (B) to (C) falls within a range of from 1/9 to 9/1, still preferably from 2/8 to 8/2. See column 3, lines 30-60. Furthermore, Jokura teaches regulating the pH value of the skin cosmetic, which contains the components (B) and (C), to pH 3 to 10, still preferably to pH 3 to 9, to avoid the irritation observed at a pH value less than 3 or exceeding 10. see column 3, lines 60-65.

When oily substances are used as the carrier, the content of the oily substance in is a range from 0.01 to 50% by weight. See column 4, lines 14-16. When water, ethanol and/or water-soluble polyhydric alcohols are employed as the carrier, the content is preferably from 0.01 to 95% by weight. See column 4, lines 30-35.

Specifically, example 3 teaches a sunscreen lotion comprising an organic acid, 0.5% of an organic acid salt (specifically sodium fumarate), and 2% 4,4-t-butyl-methoxybenzoylmethane (component ii with the instant UV range), among other components.

Jokura et al do not exemplify the instant malonic acid salt among the various dicarboxylic acid salts disclosed or the instant amine salts. Further, Jokura does not specify the acid to salt molar ratio.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Jokura et al and utilize the instant malonic acid salt in the sunscreen lotion of example 3 of Jokura. One would have been motivated to utilize the instant malonic acid salt versus the exemplified sodium fumarate (fumaric acid salt) of example 3 with a reasonable expectation of success since Jokura teaches **malonic** acid,

succinic acid, **fumaric** acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid are *all* suitable dicarboxylic acid for the composition. Therefore, the selection of the instant acid salt is considered prima facie obvious since the prior art teaches that the criticality of selecting the acid is that it is a dicarboxylic acid and not the selection of the specific dicarboxylic acid itself.

Regarding the neutralization ratio, although Jokura does not specify the molar ratio of acid: salt, it would have been obvious to a skilled artisan to manipulate this ratio. One would have been motivated to manipulate the ratio of the salt to acid since partial or full neutralization of the acid by the salt (salt acts as the neutralizing agent), adjusts the pH of the composition. Thus, one would have been motivated to utilize the desired acid: salt ratio depending on the desired pH of the composition. For instance, Jokura teaches the importance of avoiding skin irritation due to the acid; thus the pH must be above 3 and below 10 (see column 3, lines 30-65). Therefore, a skilled artisan would have been motivated to use a sufficient amount of salt to either partially or fully neutralize the acid in the composition to render a pH that does not irritant the skin wherein using equimolar amounts of the salt and acid (full neutralization) would increase the pH whereas partial neutralization of the acid would decrease the pH since the compound is in an acidic form. Additionally, it should be noted that generally differences in concentrations do not support the patentability of subject matter that is encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

B) Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495) in view of JP 61215318 to Sadashige (entire document).

As set forth above, Jokura teaches a skin cosmetic containing having an excellent moisturizing effect comprising: (A) a ceramide or a pseudoceramide; (B) a dicarboxylic acid; and (C) a salt of a dicarboxylic acid. See abstract. Jokura teaches examples of the dicarboxylic acid (B) include **malonic** acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid . The dicarboxylic acid salt (C) include alkali metal (for example, **sodium**, potassium) salts; alkali earth metal (for example, calcium, magnesium) salts; alkanolamine (for example, **triethanolamine**) salts; basic amino acid (for example, lysine, arginine) salts and **ammonium** salts. Specifically, example 3 teaches a sunscreen lotion comprising an organic acid, 0.5% of an organic acid salt, and 2% 4-tert-butyl-4-methoxybenzoylmethane, among other components.

However, Jokura does not teach the instant sunscreen agent (4,4-t-butyl-methoxydibenzoylmethane) .

Sadashige teaches a skin composition reducing discoloration and lowering UV-absorptivity. The composition contains **(i)** an organic acid or its salt wherein the acid may be selected from glyconic acid, ascorbic acid, succinic acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant **malonic** acid, valeric acid, formic acid, acetic acid, or propionic acid; **(ii)** 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane (an organic sunscreen agent having a chromophoric group active within the ultraviolet radiation range of 280 to 400 nm and referred to as Parsol 1789), and **(iii)** an emulsion base (carrier). It should be noted that 4-(1,1-dimethylethyl)-4-methoxydibenzoylmethane is also known as 4,4-t-butyl-methoxydibenzoylmethane as recited in dependent claim 6. The reference teaches the addition of the organic acid salt in combination with the instant sunscreen reduce discoloration of the

composition. Generally the composition comprises 5% of Parsol 1789, 0-0.5% of the organic acid and/or salts, and a carrier in the instant amount. Preferably the organic acid and or salt is used in a range of 0.1-0.5%. See test example 1. The examples teach composition that comprise 1) the organic acid by itself, 2) the organic acid salt by itself, and 3) the combination of the organic acid and organic acid salt. Further, the examples utilize a sodium salt of the organic acid. For instance, examples 3 and 4 teach sodium citrate and example 1 teaches sodium lactate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to combine the teaching of Jokura et al and Sadashige and utilize the instant sunscreen agent (4,4-t-butyl-methoxydibenzoylmethane). One would have been motivated to do so since Sadashige teaches methoxydibenzoylmethane is an effective sunscreen agent. Thus, a skilled artisan would have been motivated to substitute Jokura's methoxybenzoylmethane's derivative with the instantly claimed methoxydibenzoylmethane since Sadashige teaches the instantly claimed sunscreens an effective UV absorber. Further, a skilled artisan would have expected similar results and success since both Jokura and Sadashige teach the use of organic acid salts in the compositions. For instance, Jokura teaches the salts of <u>malonic</u> acid, <u>succinic</u> acid, <u>fumaric</u> acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid and it salts with a sunscreen and Sadashige teaches salts of gluconic acid, ascorbic acid, <u>succinic</u> acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant <u>malonic</u> acid, valeric acid, formic acid, acetic acid, or propionic acid with a sunscreen.

(10) Response to Argument

A) Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495).

Appellant argues that Jokura is concerned with achieving moisturization and not using dicarboxylic acids in the stabilization of sunscreen agents. Appellant argues that the instant invention has solved the problem concerning degradation of sunscreens. Appellant argues that Jokura does not exemplify malonate salts and Jokura exemplifies fumaric acid in pertinent example 3. Thus, it is argued that there is not motivation to substitute the instant claims malonate salt with the exemplified fumarate salt for the solving the problem of stability.

Firstly, the examiner points out that a reference need not exemplify an embodiment to anticipate or render an invention obvious. The examiner points out that although malonic acid is not exemplified, malonic acid is taught and it does not appear in a "laundry list" as argued by appellant. The acids taught by Jokura are sufficiently limited (malonic acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid). With regard to the salt, Jokura teaches the salt of the dicarboxylic acid may be 1) alkali metal (for example, sodium, potassium) salts; 2) alkali earth metal (for example, calcium, magnesium) salts; 3) <u>alkanolamine (for example, triethanolamine)</u> salts; 4) <u>basic amino acid (for example, lysine, arginine) salts</u> and 5) <u>ammonium salts</u>. Note that the term amine encompasses Jokura's alkanolamines, basic amino acids (lysine and arginine), and ammonium. Therefore, it is the examiner's position that although Jokura does not exemplify malonic acid or the amine salt, this does not constitute a teaching away since clearly the prior art clearly discloses the malonic acid and the amine salt. The examiner respectfully submits that disclosed examples and preferred

embodiments do not constitute a teaching away form the broader disclosure or nonpreferred embodiment as set forth in *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Thus, the motivation to utilize the malonate salt rather than the exemplified fumarate salt comes from Jokura *itself*.

Secondly with regard to the neutralization ratio, although Jokura teaches neutralization of the acid with a salt, the examiner notes that Jokura does not specify the molar ratio of the partially to fully neutralized acid. However, it is the examiner's position that the lack of exemplification of the instant ratio is not equivalent to "a teaching away" or a lack of obviousness as asserted by appellant. Hence, the premise of the obviousness rejection is based the examiner's position that the manipulation of the neutralization ratio is prima facie obvious, which will be discussed in detail below.

With regard to appellant's argument that the dicarboxylic acids are utilized for a different purpose than the appellant, the examiner respectfully points out the fact that applicant has recognized another advantage, i.e. the malonic acid salts also functions to stabilize compositions comprising sunscreens, which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In instant case, the instant claims are directed to a malonic acid salt and organic sunscreen agent having a chromophoric group active with a UV range of 280 to 400 nm. The prior art teaches a composition comprising (i) an organic sunscreen agent with a chromophoric groups active with a UV range of 280 to 400 nm and (ii) and a dicarboxylic acid salt which may be selected from *malonic* acid, succinic acid, fumaric acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid. The fact

that Jokura may use the malonic acid salt for a different purpose than the applicant is irrelevant since the prior art composition teaches the same composition with the claimed elements. Therefore, the examiner respectfully submits that the motivation to substitute the exemplified dicarboxylic acid salt with the instant malonic acid salt does not need to be the same as appellant since the same product is obtained regardless of the motivation to utilize malonic acid. The examiner further notes that appellant's arguments are based on the inventive concept of stabilizing a sunscreen composition with the malonic acid salts; i.e. a method of stabilizing a composition with malonic acid salts. However, appellant is claiming a composition comprising malonic acid salt and a sunscreen.

Appellant argues that Jokura et al teach a having a combination of the unneutralized acid (free acid) and a partially neutralized acid. Appellant argues that "the free acid can only co-exist with a partially neutralized salt because of pKa considerations" and all three species (free acid, partially neutralized acid, and neutralized acid) cannot coexist.

As acknowledged by appellant, neutralization of an acid is based on pH consideration (wherein the existence of partially neutralized acid to fully neutralized acid provides a desired pH,; however the examiner respectfully disagrees that the free acid, partially neutralized acid, and a fully neutralized salt cannot coexist.

The acid/base equilibrium equation is known to one of ordinary skill in the art and is as follows for a dicarboxylic acid, such as malonic acid, in an aqueous solution:

$$HO_2CCH_2CO_2H \xrightarrow{K_{a1}} HO_2CCH_2CO_2^- + H^+ \xrightarrow{K_{a2}} O_2CCH_2CO_2^{2-} + 2H^+$$

formula (I) formula (II)

K_{a1} and K_{a2} are the equilibrium constant for each neutralization reaction (acid equilibrium) and formula (I) and (II) represent the instant formulas as recited in the claims. The X counter ion is not included in the equation. This is standard convention to those of ordinary skill in the art since the counter ions are not reactants or products that participate in the acid-base reaction. Instant formula (I) (the partially neutralized salt form) is equivalent in solution to the singly deprotonated formula (I) shown in the above equation (i.e. one acid moiety has been "neutralized), and instant formula (II) (the fully neutralized salt) is equivalent in solution to the doubly deprotonated formula (II) shown in equation above (i.e. two acid moieties having been "neutralized").

The free acid, partially neutralized acid, and fully neutralized acid, exist in solution in equilibrium with one another, with the concentration of the different forms being governed by the individual K_a of each neutralization reaction. For example, as known to those of ordinary skill in the art, the equilibrium constant Ka_2 for the ratio of the concentration of the "fully neutralized" products (formula II) to concentration of the "partially neutralized" reactants (formula II) is expressed as:

K_{a2} = [concentration of products]/ [concentration of reactants]

$= 2[H^+]\,[O_2CCH_2CO_2^{2-}]/\,[H^+]\,[HO_2CCH_2CO_2^-]$

$= [H^+]\,[O_2CCH_2CO_2^{2-}]/\,[HO_2CCH_2CO_2^-]$

The equilibrium constant is a "constant" for a given reaction; thus the concentration of products and reactants will shift when the concentration of any of the products or reactants are changed in solution, in order to achieve the equilibrium K_a value. This concept is known as LeChatelier's Principle and is found in high school and college chemistry books. Adding

reactants to the solution creates a ratio of [products]/[reactants] that is lower than the K_a at equilibrium; thus the reaction will proceed in the forward direction to form more product, until a ratio of [products]/[reactants] that equals the equilibrium constant K_a is achieved. Similarly, increasing the concentration of any of the products, such as (H+) or $[O_2CCH_2CO_2^{2-}]$ creates a ratio of [products]/[reactants] that is too high, and causes the (reaction to proceed in reverse to form more reactants, until the equilibrium ratio K_a of the products to the reactants is achieved. Thus, adding or removing amounts of the product (H+) to the solution results in the formation of more reactants, i.e. the partially neutralized salt, and effectively changes the ratio of partially to fully neutralized acid forms.

The effect of changes in the concentration of $[H^+]$ on the equilibrium amounts of the products and reactant can also be seen by rearranging equation 2:

$K_{a2}/[H^+] = [O_2CCH_2CO_2^{2-}]/[HO_2CCH_2CO_2^-]$

The right hand side of the equation is equivalent to the ratio of fully neutralized: partially neutralized acid, the inverse of the ratio as is recited in claim 1 and 6. Thus, as K_{a2} is a constant for the given acid, malonic acid, the ratio of partially neutralized acid to fully neutralized acid will be dependent upon the concentration of H^+ in solution. In other words, the ratio of partially neutralized to fully neutralized acid is governed by the pH of the solution

($pH = -\log[H^+]$). That is, solutions having the same pH should have the same or similar ratios of partially neutralized to fully neutralized salts. It is conventional knowledge in the cosmetic art that extremely low pH (acidic) or extremely high (basic) irritate the skin; this is evidenced by Jokura's teaching that a pH value of below 3 or exceeding 10 causes skin irritation. Jokura teaches a pH range of 3 to 10, preferably 3 to 9, and exemplifies a pH of 4.1 This pH

range encompasses the generally accepted pH of 7 (neutral pH) that is considered nonirritating and suitable for cosmetic products. Although appellant does not specify a pH the instant composition, it is noted that the instant composition is directed to a "cosmetic composition" that is applied to human skin. Thus, absent evidence to the contrary, the pH of the inventive cosmetic must have a pH range of 7; or in a range that is close to 7; or have a pH range that falls within the prior art's pH range of 3 to 9. It is the examiner's position that the prior art and the instant composition would have close (to render it obvious) if not an overlapping pH. Therefore, the ratio of partial to neutralized acid would be similar. Moreover, it respectfully pointed out that is within the skill of the art to manipulate this ratio to render the desired and optimal pH. Jokura cautions that a pH value of below 3 or exceeding 10 causes skin irritation and Jokura teaches varying the free acid to acid salt to manipulate the pH within this range. Thus, a skilled artisan would have been motivated to manipulate this ratio of free acid to the acid salt as taught by Jokura et al, which would thereby simultaneously manipulate the ratio of the partially neutralized to fully neutralized acid to render a pH that is non-irritating to the skin. Thus although the prior art does not expressly disclose the manipulation of the partial to fully neutral acid salt itself, this step is *implicit* when the pH of the composition is adjusted. Therefore, the examiner respectfully submits that differences in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical as set forth in *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In instant case, appellant has not shown the unexpectedness of the instant neutralization ratio.

B) Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jokura et al (5,641,495) in view of JP 61215318 to Sadashige (entire document).

Appellant argues that JP '318 to Takada Sadashige is concerned with a similar problem of stability and using organic acid and/or their salts to prevent discoloration of sunscreen products. Appellant argues that JP '318 does not disclose amine cationic counterions of malonic acid and does not exemplify malonate salts. Appellant argues that Jokura only teaches the dicarboxylic acid salts for moisturization and does not attribute unique properties to amines. Appellant argues that Jokura does not exemplify amine salts or its effectiveness in color stabilization. Thus, it is argued the two references cannot be combined.

The merits of Jokura have been addressed above. Firstly, it is again respectfully reiterated that the instant claims are directed to a product and *not* a method of stabilizing a composition comprising sunscreens. Secondly, the examiner points out that JP '318 is relied upon for its specific teaching of the instant sunscreen. Jokura teaches the salt of the dicarboxylic acid may be 1) alkali metal (for example, sodium, potassium) salts; 2) alkali earth metal (for example, calcium, magnesium) salts; 3) alkanolamine (for example, triethanolamine) salts; 4) basic amino acid (for example, lysine, arginine) salts and 5) ammonium salts. Note that the term amine encompasses Jokura's alkanolamines, basic amino acids (lysine and arginine), and ammonium. Thus, JP '318 need not teach amine salts since Jokura is *not* deficient in this teaching.

With regard to JP '318, the examiner again respectfully submits that JP '318 does not need to exemplify malonic acid or its salt since firstly Jokura is not deficient in this sense and the motivation to combine the references is not based on the use of malonic acid salt. Rather the premise of the obviousness rejection is based on the motivation to utilize the instant sunscreen in dependent claim 6. The examiner notes that appellant attacks the references individually and has not addressed the examiner's motivation to combine the references.

Appellant argues that not all of the dicarboxylic acids taught by Jokura would provide color stabilization of sunscreens. Again the examiner notes that the claims are directed to a product and not a method of stabilization; thus the examiner need not provide Jokura's composition is stable. However, the examiner notes that Jokura teaches <u>malonic</u> acid, <u>succinic</u> acid, <u>fumaric</u> acid, maleic acid, glutaric acid, adipic acid, phthalic acid, and terephthalic acid and it salts. As acknowledged by appellant, Takada Sadashige is concerned with the same problems as the instant invention. The examiner notes that JP '318 teaches gluconic acid, ascorbic acid, <u>succinic</u> acid, citric acid, lactic acid, tartaric acid, butyric acid, oxalic acid, instant <u>malonic</u> acid, valeric acid, formic acid, acetic acid, or propionic acid and its salt provide the color stabilization. Therefore, the examiner points out that although Jokura may not have recognized the ability of some of the acid salts to stabilize the composition, this mechanism would naturally occur by following the teachings of Jokura.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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